

## **REMARKS**

### **I. Preliminary Remarks**

The Claims were subject to a Restriction Requirement. Applicants acknowledge and appreciate the rejoinder of Groups I and II, which results in claims 1-18 being under examination.

Upon entry of this paper, 1-2 and 5-18 are pending. Claims 3-4 are canceled. Claims 19-28 are withdrawn. Withdrawn claims are withdrawn without prejudice in an effort to favorably advance prosecution of the present application. Applicant reserves the right to pursue the subject matter of the withdrawn claims in a continuing application, or to have such claims rejoined in the current application. Support for the amendments to the claims is found throughout the specification. The amendments do not include new matter.

In this response, Applicant addresses each of the rejections and objections raised by the Examiner. Reconsideration and withdrawal of the rejections and objections are solicited for the reasons set out below. Applicant therefore respectfully submits that the present application is in condition for allowance. Favorable consideration of all pending claims is respectfully requested.

This Response is timely filed. The USPTO is given authorization to charge Deposit Account No. 16-1445 for any fees necessary with the submission of this Response.

### **II. Patentability Arguments**

#### **A. The Rejection of Claims 1-18 under 35 USC §112 Second Paragraph may Properly be Withdrawn.**

It is well settled that the definiteness of a claim is not judged in a vacuum. Instead the claim must be viewed in the context of the disclosure of the application from which it is derived. The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification. Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1 USPQ2d 1081 (Fed. Cir. 1986). See also BJ Services Co. v. Halliburton Energy Services, Inc. 338 F.3d 1368, 1372, 67 USPQ2d 1692, (Fed. Cir. 2003): "The question becomes whether one of ordinary skill in the art would understand what is claimed when the claim is read in light of the specification."

**1. The rejection of claims 1-4 under 35 USC §112 second paragraph may properly be withdrawn.**

The Examiner states that "Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: (1) The X-ray diffraction spectrum peaks, (2) a melting point, (3) IR spectroscopy data, (4) H-NMR spectroscopy data, and (5) DSC data." Applicants respectfully traverse this rejection.

Applicants have amended claims 1 and 2 to include the PXRD data from claims 3 and 4, respectively, and canceled claims 3 and 4. Claims 1 and 2 include the five strongest peaks from the PXRD patterns for polymorph form II (claim 1) and polymorph form I (claim 2). Only one peak is similar between the PXRD patterns of the two polymorphs. Within the disclosure, the Applicants have fully defined polymorphs (see paragraphs 0042-0046); described how to make polymorph I (see paragraphs 0106 and 0107) and polymorph II (see paragraph 0108); described the analytical methods for determination of the identity and physical properties of the polymorphs, including 1) estimation of the solubility of a polymorph in various solvents, 2) determination of the pH-solubility profile, 3) PXRD diffraction, 4) Differential Scanning Calorimetry, 5) Polarized light Microscopy, 6) Fourier-Transformed Infrared Spectroscopy, 7) Fourier-Transformed Raman Spectroscopy, and 8) Rotating Disc Intrinsic Dissolution Rate (see paragraphs 0058-0075); and presented the results of these methods (see paragraphs 0077-0104). As demonstrated in the results, the intrinsic dissolution rate of polymorph II is three times that of polymorph I (see paragraph 0088). Two distinctive PXRD patterns were observed in two batches of 5-[5-fluoro-2-oxo-1,2-dihydroindol-(3Z)-ylidenmethyl]-2,4-dimethyl-1H-pyrrole-3-carboxylic acid (2-pyrrolidin-1-ylethyl)-amide (see paragraph 0091 and figure 1). In addition, spectral variations are clearly observed in the IR and RAMAN spectra data for the two forms (see paragraphs 0093 and 94 and figures 2 and 3). Finally, the polarized light microscopy (paragraph 0096) and DSC (paragraph 0099) demonstrated differences between polymorphs I and II.

Given the explicit teachings of the specification referred to above with respect to the characteristics of polymorphs I and II, the Applicants submit that one skilled in the art, upon reading the claims and the specification, would clearly be able to identify polymorphs I and

II. Thus, based on the remarks presented herein and the cancellation of claims 3-4, the rejection of claims 1-4 under 35 U.S.C. 112, second paragraph, is overcome. Withdrawal of the rejection is therefore respectfully requested.

**2. The rejection of claims 5-12 under 35 USC §112 second paragraph may properly be withdrawn.**

The Examiner states that "Claims 5-12 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: (1) The X-ray diffraction spectrum peaks, (2) a melting point, (3) IR spectroscopy data, (4) H-NMR spectroscopy data, and (5) DSC data." Applicants respectfully traverse this rejection.

Claims 5-12 have been amended to ultimately depend from either claim 1 or claim 2. Claims 1 and 2 have been amended to distinctly claim the subject matter which Applicants regard as their invention. (see discussion in section 1 above) Given the explicit teachings of the specification, Applicants submit that one skilled in the art, upon reading the claims and the specification, would clearly know the claimed invention. Thus, based on the remarks presented herein the rejection of claims 5-12 under 35 U.S.C. 112, second paragraph, is overcome. Withdrawal of the rejection is therefore respectfully requested.

**3. The rejection of claims 5-12 and 18 under 35 USC §112 second paragraph may properly be withdrawn.**

The Examiner states that "Claims 5-12 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, Claims 5-12 are each drawn to "A composition comprising polymorph [I or II] of a compound of formula I, wherein polymorph [I or II] comprises more than about [85 to 99] weight percent of the composition." The phraseology, "more than about" is ambiguous on its face." Applicants respectfully traverse this rejection.

Claims 5-12 have been amended to replace the term "more than about" with the term "at least", rendering this rejection moot. Claim 18 depends from claims 1 or 2, and claims 1 and 2 have been amended to distinctly claim the subject matter which Applicants regard as their invention. (see discussion in section 1 above) Thus, based on the remarks presented

herein the rejection of claims 5-12 and 18 under 35 U.S.C. 112, second paragraph, is overcome. Withdrawal of the rejection is therefore respectfully requested.

**4. The rejection of claims 13-17 under 35 USC §112 second paragraph may properly be withdrawn.**

The Examiner states that "Claims 13-17 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: (1) The X-ray diffraction spectrum peaks, (2) a melting point, (3) IR spectroscopy data, (4) H-NMR spectroscopy data, and (5) DSC data." Applicants respectfully traverse this rejection.

Applicants appreciate Examiner's observation that product-by-process claims would be duplicative of claims 1 and 2. Applicants have followed Examiner's suggestion to amend claims 13-17 to be process claims dependent upon claims 1 and 2. Claims 1 and 2 have been amended to distinctly claim the subject matter which Applicants regard as their invention. (see discussion in section 1 above) Thus, based on the remarks presented herein the rejection of claims 5-12 under 35 U.S.C. 112, second paragraph, is overcome. Withdrawal of the rejection is therefore respectfully requested.

**B. The rejection of claims 5-12 under 35 USC §112, first paragraph may properly be withdrawn.**

The Examiner states that "Claims 5-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification (including knowledge readily known by a PHOSITA), while being enabling for solid compositions comprising polymorphs I or II, does not reasonably provide enablement for liquid compositions comprising polymorphs I or II. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims." Applicants respectfully traverse this rejection.

Applicants have followed Examiner's suggestion to amend the composition claims to reflect that the compositions are solid in form. In view of the foregoing, Applicants respectfully submit that the rejection of claims 5-12 under 35 U.S.C. §112, first paragraph, is thus overcome. Withdrawal of this rejection is respectfully requested.

**C. The Anticipation Rejection of Claims 5-12 under 35 U.S.C. §102(b) May Properly Be Withdrawn.**

A patent is invalid for anticipation under 35 USC 102(b) if a single prior art reference identically discloses each and every limitation of the invention as set forth in the claims. (Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987)). The prior publication must disclose in an enabling manner the invention that is in question. The exclusion of a claimed element, no matter how insubstantial or obvious, from a reference is enough to negate anticipation. (Connell v. Sears, Roebuck & Co., 220 U.S.P.Q. 193, 1098 (Fed. Cir. 1983)). Applicant respectfully submits that these criteria are not met in the Examiner's rejection. The claims, therefore, are not anticipated by the references.

The Examiner stated that "Claims 5-12 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Publication No. 2002/0010203" (corresponding to U.S. application No. 09/741,842 to Lipson, et al.). Applicants respectfully traverse this rejection.

The '203 publication does not describe or enable polymorphs form I or II of a compound of formula I, nor does it disclose or suggest their uses. According to the invention, the compound of formula I surprisingly exists in two polymorphic forms that exhibit different physical properties. The '203 publication discloses the compound per se and makes no mention of this compound existing as polymorphs. Thus, the '203 publication does not anticipate the claimed invention because it fails to disclose each element of the instant claims in an enabling manner.

Based on the remarks presented herein, the rejection of claims 5-12 under 35 U.S.C. 102(b) is overcome. Withdrawal of the rejection is therefore respectfully requested.

**D. The Objection to Claims 3, 4, 6-8, 10-12, and 16-18 May Properly Be Withdrawn.**

The Examiner stated that "Claims 3, 4, 6-8, 10-12, and 16-18 are objected to as they are based on a rejected base claim." Applicants respectfully traverse this rejection.


Applicants have amended the base claims (see above discussions) thus rendering this objection moot. Withdrawal of this objection is respectfully requested.

**III. Conclusion.**

In view of the amendments and remarks made herein, Applicants respectfully submit that Claims 1-2 and 5-18 are in condition for allowance and request notification of same.

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Respectfully submitted,

  
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